Remarks

The claims under direct examination are claims 26-44. As explained below it is hoped that with the current restriction on the basic method claim, claim 45, the entire claim set, 26-49 will be allowable should the device claims be allowed.

There are no drawing changes required as the one claim mentioning an organ has been amended to remove this commonly understood reference in light of the specification.

Further the examiner is mistaken in identifying the structures in Figures 4a-e as light guides; or is confusing if this was not the intent of this sentence. There are no light guides in these figures, nor are any described as being there. The tubes used to form the paraboloidal shapes of the curable fluids are just that. They maintain a surface and volume to contain the curable diffusion medium until each one can be cured into a solid paraboloidal shape. The diffusor's formed in Figure 4 are specifically described in the specification to be those used in Figure 2. (published specification, paragraph 0029) Since no one has yet described the use of paraboloidal shaped diffusing mediums, it is instructive to the full invention of 'light applicator with diffusor' to provide and secure a method producing such unique structures. For searching purposes, the claims for the device itself are a provident way to go. Once the structure/device claims are established as allowable, the method of producing them should be rejoined. To aid in doing this the method claim 45 is, as originally intended, tied directly to the production of the embodiments claimed in claims 26-44.

The word "diffusor" in the claims is the consistent spelling for such a device as described throughout the specification. In the papers and correspondence of the inventors this is the spelling they used for the title. The title could be changed to reflect this, however, every English dictionary, especially the Webster Collegiate Dictionaries, that we have consulted states that 'diffusor' and 'diffuser' are equivalent and accepted spellings with the same meanings. Thus this is not a major problem for anyone skilled in the art of distributing light from tips of optical fibers. We speak from 25+ years in the optical fiber field. The claim language has been unified under 'diffusor' language to minimize concern, and because this spelling is predominantly used in the specification.

As to the suggested other ambiguous terminology items, within claim 26; first 'is attachable' cannot and does not mean an item "may or may not be able to attach". The

proper parsing of the phrase indicates that it clearly states that the diffusor is able to be attached. It does mean that the diffusor can be attached to a light guide, but is being claimed independent of having to always be attached to the light guide. To use 'is attached' as suggested would mean the that the device being patented is a light applicator with a diffusor always connected to a light guide. This is an expansion of the invention as described and an unnecessary complication.

The language of claim 26 "A light applicator with a diffusor which is attachable..." follows a well established English use of language and especially in the field of fiber optics for medical applications from whence those skilled the art of this invention come from. Claim 26 and all dependent claims therefrom are understood to describe an invention for a 'light applicator with a diffusor'. There can be several kinds of light applicators, not all of which are able to diffuse light. In the specification from the introductory paragraph 0001 (published specification), it defines this entire invention is about "a light applicator with a diffusor which is attachable...". Those skilled in the art as well as anyone familiar with articles or patents would understand that, within the text, a light applicator would always mean 'a diffusor which is attachable..' Interchanging the two terms would not confuse the readers. In the claims the two terms are described in the proper hierarchy and constantly maintained that way.

As to the concern with 'the diffuser will overlap with respect to a line-of-sight aligned in at a right angle', this would be quite ambiguous if it was the language used in the claim. Presuming the examiner meant to question "..in which different diffusing regions with different scattering... and in which the diffusion regions will overlap with respect to a line-of-sight aligned at a right angle to the light axis"... ; the 'limitations' are clearly discernable and understood as the following breakdown unfolds. The 'light axis' of the device is understood as be along the longitudinal axis of the light guide into the longitudinal axis of the diffusor/light applicator' i.e. the optical axis **6** of Figure 1. Since a diffusor is used to move emitted light radiation from this axis at some angles, one understands a line-of-sight direction needs to be explained in relation to the optical axis. Here the claim specifically identifies a unique angle, i.e. aligned at a right angle to the light axis. This well specifies how one need look at the diffusor-light applicator to observe the overlap of

37. (presently amended) A light applicator according to claim 35, wherein the concentration of scattering centers along the optical axis as averaged over the cross sectional surface area shows a minimum between the proximal end and the distal end of the diffusor .
38. (original) A light applicator according to claim 32, wherein the distribution of light through the light-emitting surface of the reflections element and through the light-emitting surface of the diffusor is homogeneous.
39. (presently amended) A light applicator according to claim 26, wherein the diffusion regions are produced [~~on the basis of~~] using silicone as a curable, liquid diffusion medium.
40. (presently amended) A light applicator according to claim 26, wherein scattering [~~centers~~] particles present in the diffusion regions are [~~produced on the basis of~~] TiO_2 or $BaSO_4$.
41. (original) A light applicator according to claim 26, wherein the diffusion regions are enclosed by a covering which has smaller refractive index than the refractive index of the diffusion regions
42. (original) A light applicator according to claim 26, whose light-emitting surfaces are covered by a partly backscattering layer.
43. (presently amended) A light applicator according to claim 26, whose diffusor's tube portion is [~~provided with~~] flexible[~~-configuration~~].
44. (presently amended) A light applicator according to claim 26, whose diffusor's tube portion is [~~provided with a~~] rigid[~~-configuration~~].
45. (presently amended) A method for producing a diffusor/(light applicator), according to claim 26, which is connectable to a light guide and in which different diffusion regions with different scattering parameters are formed along an optical axis of the light guide prolongated into the diffusor, wherein:
    - a hollow body is used for the diffusor which is filled at least in sections with a first diffusion medium,
    - a second diffusion medium is injected into the first diffusion medium and
    - tin the first diffusion medium a boundary surface shaped according to a laminar flow profile is formed between the first diffusion medium and the second diffusion medium as a result of the laminar flow of the second diffusion medium in the first medium.
46. (original) A method according to claim 45, wherein the boundary surface is formed inn a paraboloidal way.
47. (original) A method according to claim 45, wherein the first diffusion medium and the second diffusion medium are each sucked into the hollow body.
48. (original) A method according to claim 45, wherein the second diffusion medium is injected from a first end of the hollow body into the first diffusion medium and a third diffusion medium is injected from a second end of the hollow body into the first diffusion medium.
49. (original) A method according to claim 45, wherein the diffusion media are cured.

different diffusion regions as shown in the Figures 1-3. Referring to the exact words used in claim 26, the limitation is fully described with references that can be checked in the Figures and the specification description of the figures.

The terms 'laminar flow profile', especially in light of the figures 1-4 and description of these figures, are well appreciated and generally understood by persons knowledgeable in the art of diffusor production. As explained in paragraph [0034] of the published specification, laminar flow and the drawing in of the different scattering fluids produce a distinctive distribution of the two fluids within the tube section. In particular a parabolic portion of the second filled medium extends into the first filled medium as best illustrated in figures 1, 3 and 4B. One skilled in the art of medical devices/diffusors would not have a problem to understand the limitation defined by the 'laminar flow profile'. Simply speaking this refers to the fluid near the walls of the tube portion moving slower than fluid near the center of the tube's cross section; and the consequent interface forming between discernable fluids within the tube.

As to claim 35, it is a well accepted convention in medical device technology to refer to a proximal end and a distal end for an elongated component of a system which enters a patient's body or needs to be pointed towards a treatment site on a patient. The proximal end is the end of the component which is closest to the energy source, the a laser or light source. The distal end is the end closest to a treatment site or deeper into a patient's body than a proximal end would be. The 'proximal diffusion regions' of the applicator would be the diffusion region or regions nearest the end of the light guide fiber (**3**) in figure 1-3, for example. The distal diffusion region would thus be at the end of the application farthest from the light guide entry. More clearly, the 'proximal diffusion region' is defined in figures 5-7 as item **7** in each of these figures. This clearly identifies where it is and where a 'local maximum' of emitted light would occur. As to the antecedent problems pointed out by the examiner the claim has been amended to remove them.

Claim 34 was amended to remove reference to a patient's organ, which is not illustrated in the drawings. It deals specifically with item **33** exemplified in figure 6.

Claims 39, 40 and 43, 44 were each amended to remove ambiguity concerns of the examiner.

As to the various 35 USC §103 obviousness concerns based primarily on a published patent application by Bays et al., US 2005/0165462, the following observations and criticisms are presented. Included in attachments is information and Declaration of the inventors that the work of the present invention had been completed, except for filing long before the priority date of the provisional filed by Bays et al.

Besides the priority issue as to whether the disclosures of Bays et al. were done ahead of the present invention, there are a few concepts exposed in the present invention which are not discussed or implied in the prior art.

First let us confirm that the language of claims 32 through 38 deal with embodiments of the special devices for gynecology, etc. which are described in Figures 5-7. Here the mirrored surface is around the proximal end of the applicator and functions essentially diametrically opposite than the mirror taught and discussed in Bays, e.g. paragraph 0004, last line is left column. The mirror described and claimed in the present invention allows distribution and irradiation of a larger area facing the hemispherical mirror in a fairly uniform manner. The mirror, in Bays, is the rather commonly used distal end mirror to reflect central light traveling down the applicator which as noted in Bays reflects light back into the diffusing medium, which had not been scattered on its first pass through the medium. The positioning of the reflective element and its function clearly differ from the general comments provided in Bays and other prior art.

As to application of this point to the claim 28 reference to a mirror in the distal end, which is essentially the same as referenced by Bays et al., not their invention but to prior art, indeed this element is unique only in that it is an addition to the unique, non-obvious aspects of the base claim 26 on which it depends. In other words we would agree that adding the restriction of claim 28 does not make claim 26 more novel or non-obvious. It is just adding an additional item to provide another useful embodiment of the present invention.

While the figures in Bays et al. are not always clear, the description in Bays et al. on the shape of the diffusing medium sections are always referred to as cones and he demonstrates apparently collimated light in selected figures. No mention is made of parabolic shapes or paraboloids for the diffusing medium. The geometrical constraints and the distribution of scattered light from cones rather than paraboloids are mathematically

different as are the distribution restraints to obtain near homogeneous distribution of light, along the length of the diffusor, coming from a light guide entering at the proximal end of the diffusor, as desired from the present invention.

Further in Bays et al. the various scattering sections are allowed to have the same concentration and type of scattering particles as long as there is a scattering section between them. See paragraph 0057, lines 7-11. Whereas in the present invention paragraph 0026 identifies a continually increasing concentration of scattering particles progressing from the proximal end to distal end of the diffusor.

Lastly as noted earlier the research leading to the present invention was essentially completed in the fall of 2001. Evidence is presented to demonstrate the thesis on which the invention is based was submitted in October of 2001 and formally accepted in November, 2001 on the dates shown in the attachments. The Declaration also indicates that the thesis was kept unpublished until the initial priority documents were filed in Germany in 2002.

We provide the Declaration, evidence of signed dates and sample pages of the thesis showing some embodiments of the present invention to swear back before the Bays et al. patent application priority dates. We have also provided Revocation of Power of Attorney with New Power of Attorney and Change of Correspondence Address, along with a signed Statement under 37 CFR 3.73(b) as to ownership of the patent application by the Ludwig Maximilans University of Munchen. To establish the undersigned as the proper addressee for any future actions in this docket. Our internal attorney docket # is BJA412T as noted on these papers.

With these remarks and exposition of terms within the claims it is believed that the disclosure is now in condition for further analysis and allowance. Reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Respectfully submitted,

Dated: March 28, 2007

Bolesh J. Skutnik, PhD, JD
Reg. No. 36,347
Attorney for Applicants

CeramOptec Industries, Inc.
515 Shaker Road
East Longmeadow, MA 01028
Phone: (413) 525-8222

Fax: (413) 525-0611

DECLARATION

SN: 10/511,378

Full name of first joint inventor: Wolfgang Beyer

Inventor's signature: Wolfgang Beyer

Date: 26.02.07

Residence: Gräfelfing, Germany

Citizenship: German

Mailing Address: Falkenstr. 15, D-82166 Gräfelfing, Germany

Full name of second joint inventor: Andreas Obermeier

Inventor's signature: Andreas Obermeier

Date: 24.02.07

Residence: München, Germany

Citizenship: German

Mailing Address: Werner-Egk-Bogen 27, D-80939 München, Germany

Name, Vorname: Obermeier, Andreas
Geburtsdatum: 17.11.1971
Studiengang: 06FM9M

Selbständigkeitserklärung

Diplomarbeit gemäß § 31, Abs.5 der
Rahmenprüfungsordnung
für die Fachhochschulen in Bayern

Hiermit versichere ich, dass ich diese Arbeit selbständig angefertigt, nicht anderweitig für Prüfungszwecke vorgelegt, alle benutzten Quellen und Hilfsmittel angegeben, sowie wörtliche und sinngemäße Zitate gekennzeichnet habe.

München, den 14.11.2001

Andreas Obermeier

Andreas Obermeier

Eingang im Prüfungsamt:

Datum und Handzeichen

BELEG ZUM ERFASSEN DER DIPLOMARBEIT

Obermeier, Andreas

Familienname, Vorname des Studenten/ der Studentin

FM 8M 06570896

Studiengruppe Matrikelnummer

Note der Diplomarbeit: 1

Hinweis: Es kann nur eine ganze Note gegeben werden.

Thema der Diplomarbeit:

Entwicklung eines Zerrix-Applikators für die Photodynamische Therapie PDT im Gynäkologischen Bereich

18.12.01 Dr. Schörner

Datum, Name/Unterschrift des Prüfers (Aufgabenstellers)

Datum, Unterschrift des Vorsitzenden der Prüfungskommission

1) Ausfüllen im Fachbereich
2) Weitergabe an das Prüfungsamt zur Erfassung

Im Prüfungsamt erledigt: _____
Datum, Namenszeichen

3) Ablage im Prüfungsamt

Beleg-DA-6.92

Eingang im Prüfungsamt:
20.12.2001
Datum und Handzeichen

BELEG ZUM ERFASSEN DER DIPLOMARBEIT

Obermeier, Andreas
Familienname, Vorname des Studenten/ der Studentin

FM 8M 06570896
Studiengruppe Matrikelnummer

Note der Diplomarbeit: 1

Hinweis: Es kann nur eine ganze Note gegeben werden.

Thema der Diplomarbeit:

Entwicklung eines Zervix-Applikators für die Photodynamische Therapie PDT im Gynäkologischen Bereich

18.12.01 Dr. Schörner
Datum, Name/Unterschrift des Prüfers (Aufgabenstellers)

18.12.01
Datum, Unterschrift des Vorsitzenden der Prüfungskommission

1) Ausfüllen im Fachbereich
2) Weitergabe an das Prüfungsamt zur Erfassung
Im Prüfungsamt erledigt: 20.12.2001
Datum, Namenszeichen
3) Ablage im Prüfungsamt

Beleg-DA-5.92

Fachhochschule München

University of Applied Sciences

Ludwig Maximilians Universität München

LMU

Fachbereich 06 Feinwerk- und Mikrotechnik/ Physikalische Technik
Studienschwerpunkt Medizintechnik

Department of Precision Engineering/ Engineering Physics

Diplomarbeit

zur Erlangung des akademischen Grades
Diplom-Ingenieur (FH)

Entwicklung eines Zervix-Applikators für die Photodynamische Therapie PDT im Gynäkologischen Bereich

von

Andreas Obermeier

Dozent: Prof. Dr.–Ing. J. Schörner

Betreuer: Dr. W. Beyer

Durchgeführt im Laser-Forschungslabor Urologische Klinik,
Klinikum der Universität München in Großhadern

München
Oktober 2001

LFL
Laser-Forschungslabor
Urologische Klinik
Klinikum Großhadern

Inhaltsverzeichnis

Abbildungsverzeichnis

Lichtverhältnis mit berücksichtigt. Es ergab sich je nach Streufasergesamtlänge G_w, die Zylinderlänge L_Z von der Kreisschnittfläche bis zum Beginn des Spiegels im Faserschlauch. In untenstehender **Abbildung 68** ist die sich ergebende Position des Zylinders zum Aushärten dargestellt. Die Leuchtkörperlänge L_{LK} setzt sich aus der Summe von Halbkugelradius und 3mm langen Zylinderaufsatz zusammen.

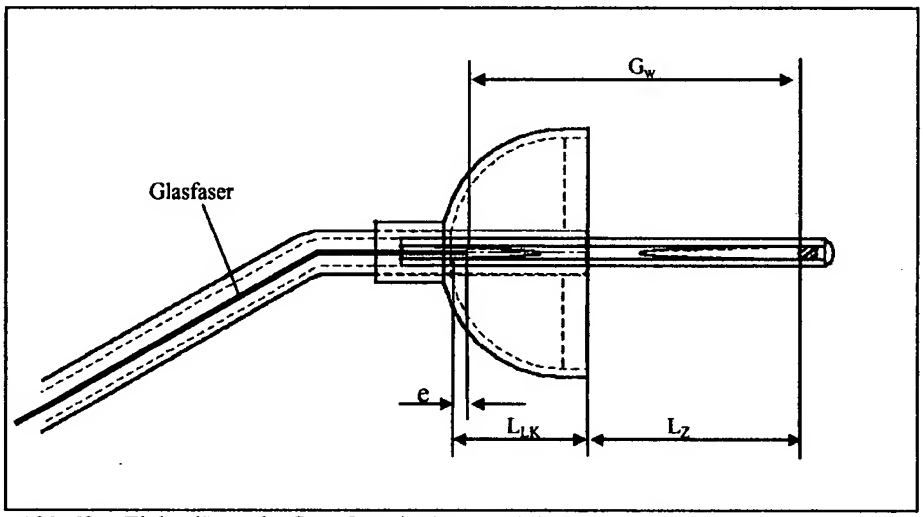

Abb.68: Einbaulänge der Streufaser in den Leuchtkörper

Damit ergibt sich die Zylinderlänge, wie folgt:

$$L_Z = G_w - (L_{LK} - e) \qquad \text{(Nr. 36)}$$

Es ergab sich eine Abweichung der angestrebten Zylinderlänge von ΔL_Z=3mm, was auf eine Schwankung der Gesamtlänge G_w der Streufaser bei der Herstellung zurückzuführen ist. Dabei lagen die Intensitätsverhältnisse der Applikatoren stets im Toleranzbereich.

7. Handstück ausgießen

Abschließend wird zur Zugentlastung das Handstück von der noch offenen Seite mit klarem Silikon ausgegossen. Hierzu wurde eine 1mm Bohrung in das Handstück, gleich nach der Streufaser, gemacht. Das Silikon wurde mit einer Spritze von der, in obenstehender **Abbildung 68** linken Seite, entlang der

Glasfaser injiziert. Vor dem Aushärten wurde noch eine Hülse, aus Messing 3x1mm und 10mm Länge, für die Zentrierung der Glasfaser am Ende des Handstücks in das Silikon eingesetzt.

8. SMA-Stecker

Nach dem Aushärten wurde abschließend ein SMA-Klebestecker am Glasfaserende montiert und über das Handstück ein weißer Schrumpfschlauch aufgebracht.

In nachfolgender **Abbildung 69** ist der komplette Zervix-Applikator dargestellt.

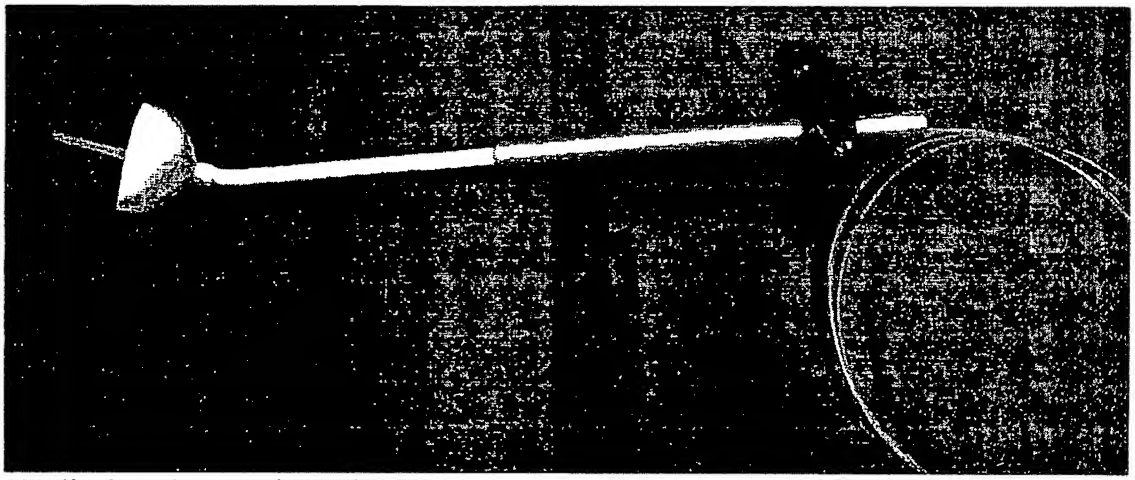

Abb.69: Kompletter Zervix-Applikator

Name, Vorname: Obermeier, Andreas
Geburtsdatum: 17.11.1971
Studiengang: 06 FM

Selbständigkeitserklärung

Diplomarbeit gemäß § 31, Abs.5 der
Rahmenprüfungsordnung
für die Fachhochschulen in Bayern

Hiermit versichere ich, dass ich diese Arbeit selbständig angefertigt, nicht anderweitig für Prüfungszwecke vorgelegt, alle benutzten Quellen und Hilfsmittel angegeben, sowie wörtliche und sinngemäße Zitate gekennzeichnet habe.

München, den 14.11.2001

Andreas Obermeier